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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,726	09/30/2003	Diane K. Burnside	23,369-155	4006

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PATENT DEPARTMENT
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EXAMINER

SNOW, BRUCE EDWARD

ART UNIT PAPER NUMBER

3738

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/674,726

Applicant(s)

BURNSIDE ET AL.

Examiner

Bruce E. Snow

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/5/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-48, 50-56, 58-62, 64, 65 and 77 is/are pending in the application.
- 4a) Of the above claim(s) 51 and 62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-48, 50, 52-56, 58-61, 64, 65 and 77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicants amendments and arguments have been fully considered. The rejection under 35 U.S.C. 102(b) as being anticipated by Fontaine et al (5,527,354) has been withdrawn because it fails to teach the graft is receptive to growth of body tissue therein.

Regarding the rejection under 35 U.S.C. 102(b) as being anticipated by Thompson et al (5,957,974), applicant argues that Thompson et al teaches a single strand which is not sufficient to provide a tubular body that is materially altered over time in vivo, in terms of a substantially reduced capacity to provide radial support. The Examiner disagrees and quotes Thompson et al, "[a]lternatively, *biological or bioabsorbable strands can be interwoven in this fashion.*" Thompson et al does not teach a single strand but multiple strands. Inherently, these strands form a bioabsorbable portion of tubular body and are reduced over time.

Applicant has submitted a terminal disclaimer which overcame the obviousness-type double patenting rejection as being unpatentable over the claims of U.S. Patent No. 6,626,939.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 36-48, 50, 52-56, 58-61, 64-65, and 77 are rejected under 35 U.S.C. 102(e) as being anticipated by Stinson (6,245,103).

Fontaine et al teaches a stent-graft comprising:

a radially compressible and radially expandable annealed a tubular body 10 comprising a bioabsorbable portion (see at least the abstract) having open ends and a sidewall structure having openings therethrough; and

a compliant graft layer 15 cooperating with the structural layer to form a stent-graft implantable at a treatment site in a body lumen, wherein the compliant graft layer tends to conform to the tubular body as the tubular body radially expands and contracts;

wherein the structural layer is radially expandable when deployed at the treatment site and thereby is adapted to fix the stent-graft at the treatment site and maintain patency of the body lumen;

characterized in that the structural layer further is adapted to be at least partially absorbed in-vivo following deployment, and the graft layer is adapted to remain at the treatment site while the tubular body is so absorbed.

See column 9, lines 38 et seq. teaching "a covering 15 or additional interwoven filaments.. used as a graft." Column 10, lines 3-4 teach "not all of the filaments consist of a bioabsorbable material", therefore, the covering made of "additional filaments" are not all bioabsorbable. Also see column 8, lines 60 et seq., teaching at least one of the filaments is bioabsorbable.

Claims 36-40, 42, 44-58, 60-63, and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Thompson et al (5,957,974).

Referring to all figures, specifically figure 13, Thompson et al teaches a stent-graft comprising:

a radially compressible and radially expandable annealed a tubular body 106, 110 comprising a bioabsorbable portion (see 13:63-64) having open ends and a sidewall structure having openings therethrough; and

a compliant graft layer 40, 108 cooperating with the structural layer to form a stent-graft implantable at a treatment site in a body lumen, wherein the compliant graft

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layer tends to conform to the tubular body as the tubular body radially expands and contracts;

wherein the structural layer is radially expandable when deployed at the treatment site and thereby is adapted to fix the stent-graft at the treatment site and maintain patency of the body lumen;

characterized in that the structural layer further is adapted to be at least partially absorbed in-vivo following deployment, and the graft layer is adapted to remain at the treatment site while the tubular body is so absorbed.

Regarding at least claims 40 and 42, see Example 3.

Regarding new claim 77, applicants use of the transistionary phrase allows for additional elements, the tubular body is interpreted as only the bioabsorbable strands (13:63-64).

All other limitations are self-evident.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 41, 43, 59 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson et al (5,957,974) in view of Stinson (6,245,103).

Thompson et al discloses the stent-graft as described above, however, fails to teach the materials used for the bioabsorbable structural layer (strands 110). Stinson teaches a similar braided stent constructed of a bioabsorbable material such as PGA or PLA. It would have been obvious to one having ordinary skill in the art to have utilized the bioabsorbable materials taught by Stinson for the bioabsorbable material of Thompson et al for their well know biocompatibility with the body, etc.

Regarding the adhesive being bioabsorbable, it would have been obvious to one having ordinary skill in the art to utilized a bioabsorbable adhesive for that taught by Thompson et al for their know biocompatibility with the body and to reduce foreign material in the body and allow for increased body ingrowth. Additionally, lacking any criticality in the specification, the use of a bioabsorbable adhesive fails to produce any advantage over that taught by Thompson et al and is therefore considered an obvious matter of design choice.

Claims 51 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stinson (6,245,103) in view of Thompson et al (5,957,974).

Stinson discloses the stent-graft as described above, however, fails to teach the materials used for the non-bioabsorbable filaments. Thompson et al teaches a similar stent-graft which uses at least PET and ePTFE for such filaments; see column 8, lines 1-14. It would have been obvious to one having ordinary skill in the art to have utilized the non-bioabsorbable materials taught by Thompson for the non-bioabsorbable materials of Stinson for their well know biocompatibility with the body, etc.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

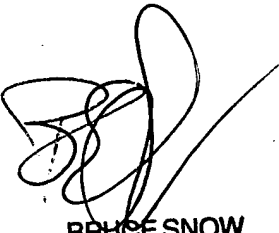
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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BRUCE SNOW
PRIMARY EXAMINER